

and the need for verification of quality by inspection and test.

(c) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall base the requirements and procedures of their quality assurance program(s) on the following considerations concerning the complexity and proposed use of the structures, systems, or components:

(1) The impact of malfunction or failure of the item on safety;

(2) The design and fabrication complexity or uniqueness of the item;

(3) The need for special controls and surveillance over processes and equipment;

(4) The degree to which functional compliance can be demonstrated by inspection or test; and

(5) The quality history and degree of standardization of the item.

(d) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to ensure that suitable proficiency is achieved and maintained.

(e) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program must regularly review the status and adequacy of that part of the quality assurance program which they are executing.

§ 72.146 Design control.

(a) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish measures to ensure that applicable regulatory requirements and the design basis, as specified in the license or CoC application for those structures, systems, and components to which this section applies, are correctly translated into specifications, drawings, procedures, and instructions. These measures must include provisions to ensure that appropriate quality standards are specified and included in design documents and that deviations from standards are controlled. Measures must be established for the selection and review for

suitability of application of materials, parts, equipment, and processes that are essential to the functions of the structures, systems, and components which are important to safety.

(b) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish measures for the identification and control of design interfaces and for coordination among participating design organizations. These measures must include the establishment of written procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces. The design control measures must provide for verifying or checking the adequacy of design by methods such as design reviews, alternate or simplified calculational methods, or by a suitable testing program. For the verifying or checking process, the licensee and certificate holder shall designate individuals or groups other than those who were responsible for the original design, but who may be from the same organization. Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, the licensee and certificate holder shall include suitable qualification testing of a prototype or sample unit under the most adverse design conditions. The licensee, applicant for a license, certificate holder, and applicant for a CoC shall apply design control measures to items such as the following: criticality physics, radiation, shielding, stress, thermal, hydraulic, and accident analyses; compatibility of materials; accessibility for inservice inspection, maintenance, and repair; features to facilitate decontamination; and delineation of acceptance criteria for inspections and tests.

(c) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the license or CoC require prior NRC approval.